UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,665	08/05/2003	Robert W. Scott	0130541	6357

7590 11/15/2007

ROBERT W. SCOTT
6315 CALOIS DRIVE
INDIANAPOLIS, IN 46220

EXAMINER	
SHAHRESTANI, NASIR	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,665	SCOTT ET AL.	
	Examiner	Art Unit	
	Nasir Shahrestani	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to Applicant's communication filed 7/30/2007.

Claim 26 has been added as new.

Claims 1-26 are pending.

Response to Arguments

Applicant's arguments filed 7/30/2007 have been fully considered but they are not persuasive. Applicants argue, as an initial point, that the present invention is for a catheter "for detecting diseased tissue in a hollow body organ" and that the '563 patent does not teach the limitation because of a difference and distinction in the purpose for the catheter is used. Examiner respectfully disagrees. The purpose and use of the catheter of the '563 patent is irrelevant when used as prior art to meet the limitation of the SYSTEM claims as presented. The function of the '563 patent is not of issue since the components are capable of performing the tasks outlined in the proposed inventions system claims. Applicants further argue that the '563 patent does not teach a fiber for emitting and receiving diagnostic light". Examiner respectfully disagrees in that the optical fiber of the '563 patent teaches light that could be classified as diagnostic depending on the use, which is emitting light. Furthermore, in order for an optical fiber to emit light, it must first RECEIVE light and since applicants claimed language does not specify WHERE the light to be received is ORIGINATED, the teachings of the '563 patent meet the limitations of said claimed language. Regarding applicant's argument of claim 18, the '178 patent reads on a "treatment optical fiber" within the broadest reasonable interpretation as the applicant has not specified in the claim language what comprises as "treatment".

Examiner further directs applicants attention to the '563 patent (column 21 lines 7-11) in that the shunt carries the optical fiber carrying light, hence the shunt corresponds to a "light transmission zone".

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7-9, 11, 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Macoviak et al. (U.S. Patent No.: 6,254,563).

Macoviak et al. teaches a catheter comprising an elongated tubular shaft (fig. 60) having a proximal end remaining outside the body organ (fig. 5) and a distal end inserted into the body organ (fig.5) and having a light transmission zone (shunt 102) through which light can be transmitted; a fiber lumen in the catheter shaft for containing a diagnostic optical fiber (actuation fiber 426) for emitting and transmitting light through the light transmission zone (col. 21 lines 2-7); a diagnostic subassembly at the proximal end (fig. 5) in communication with the optical fiber; an occlusion balloon (occlusion member 280) positioned on the distal end of the catheter shaft adjacent to the light transmission zone (fig. 7); an inflation lumen (inflation lumen 124) in the catheter shaft and in fluid communication with the balloon for delivering fluid from an inflation

fluid source at the proximal end of the catheter shaft to the balloon (col. 14 lines 12-24); an infusion lumen in the catheter shaft for delivering infusion fluid form and infusion fluid source at proximal end to distal end of catheter shaft (claims 13 & 27); one or more infusion ports (ports 114, 194, etc.) formed on or near the light transmission zone and in fluid communication with the infusion lumen for delivering fluid to the hollow body organ (col. 12 lines 20-47). Macoviak further teaches the ports are radially and longitudinally distributed around the circumference of the catheter shaft (fig. 1).

Regarding claim 7-8, Macoviak further teaches wherein the diagnostic optical fiber is in communication with a light source at the proximal end of the catheter shaft (col. 20 lines 62-65) to transmit light to issue via the transmission zone. Macoviak also teaches a second fiber lumen in the catheter shaft (member 428) for containing a light treatment optical fiber.

Regarding claim 12, Macoviak et al. further teaches the diagnostic device is an intravascular ultrasound catheter subassembly or fluorescence detection catheter subassembly (col. 8 lines 52-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15, 26, are rejected under 35 U.S.C. 103(a) as being unpatentable over Belef et al. (U.S. 6,475,226 B1) in view of Macoviak et al. (U.S. Patent No.: 6,254,563).

Belef et al. teach an elongated tubular catheter shaft (fig. 15A) with a distal end having a light transmission zone though which light can be transmitted (element 242); a diagnostic lumen in the catheter shaft for containing an optical fiber (element 245) for capturing information and a diagnostic subassembly at the proximal end (element 248) for processing information. Belef et al. also teach in another embodiment multiple lumens or a second lumen containing a tissue penetrating/treating member (element 46) in which RF energy or light energy such as a laser may be utilized to heat surrounding tissue (col. 17 lines 19-22); an occlusion balloon (element 2562) adjacent to the light transmission zone; an inflation lumen (manifold 34) in fluid communication with the balloon including on or more inflation ports (inflation port 36). Belef et al. further teach that the light source may be any infrared wavelength of light for tissue penetration/treatment (col. 18 lines 12-21).

Belef et al. do not specifically teach the use of infusion.

Macoviak et al. teach an infusion lumen in the catheter shaft for delivering infusion fluid form and infusion fluid source at proximal end to distal end of catheter shaft (claims 13 & 27); one or more infusion ports (ports 114, 194, etc.) formed on or near the light transmission zone and in fluid communication with the infusion lumen for delivering fluid to the hollow body organ (col. 12 lines 20-47).

It would have been obvious so one of ordinary skill in the art to have included infusion in order to deliver various solutions such as saline to the tissue being penetrated for well-known benefits. Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use OCT to enhance diagnosis and to expedite treatment.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macoviak et al. (U.S. Patent No.: 6,254,563) in view of Dias (U.S. Patent No.: 5,152,291). Macoviak et al. teaches all the limitations of claim 1 but does not teach wherein the diagnostic optical fiber is configured to emit and receive fluorescent light. Dias teaches the use of a single fiber for emitting and receiving fluorescence emitted from dye (col. 2 lines 58-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the optical fibers as taught by Macoviak et al. to further include a single fiber to emit and receive fluorescence from tissue since the wavelength of the emitted fluorescence is always lower than that of the input excitation.

Claims 10, 16 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macoviak et al. (U.S. Patent No.: 6,254,563) in view of Kilpatrick et al. (U.S. Patent No.: 6,716,178). Macoviak et al. teaches all the limitations of claim 1 but does not teach a temperature sensing element. Kilpatrick et al. teaches a catheter with fiber optic assembly capable of thermal sensing (col. 1 lines 9-15). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the apparatus as taught by Macoviak et al. to further include temperature sensing as taught by Kilpatrick et al. to eliminate the need for a second diagnostic device and to expedite treatment.

Regarding claim 16 and 18, Macoviak teaches an elongated tubular catheter, a first and second fiber lumen, a diagnostic subassembly, an occlusion balloon, an inflation lumen, an infusion lumen, and one or more infusion ports as described above, but does not teach the second fiber lumen containing a diagnostic optical fiber. Kilpatrick et al. teaches a second optical fiber

for performing diagnosis (col. 1 lines 9-15). Kilpatrick further teaches wherein the second optical fiber could be used for delivering treatment light to the tissue area (col. 3 line 66). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the apparatus as taught by Macoviak et al. to further include temperature sensing as taught by Kilpatrick et al. to eliminate the need for a second diagnostic device and to expedite treatment.

Regarding claims 19-23, Macoviak teaches all the limitations as described above under rejection of claim 1.

Regarding claim 24, Macoviak does not teach the use of a filter however Kilpatrick et al. teaches the use of a high-resolution filter or wavelength selective optical element (col. 13 lines 49-54). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the apparatus as taught by Macoviak et al. to further include a wavelength selective optical element as taught by Kilpatrick et al. in order to sharpen the features displayed in the spectral response for easier peak recognition and spectral analysis.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macoviak et al. (U.S. Patent No.: 6,254,563) in view of well-known practices in the art. Macoviak et al. teaches all the limitations of claim 11 but does not teach wherein the diagnostic device is an optical coherence tomography catheter subassembly or configured for visible or infrared light detection. The use of the aforementioned catheter subassemblies is well known in the art and official notice of such is taken. It would have been obvious to one of ordinary skill in the art at the time of the invention to use OCT or infrared subassemblies to enhance diagnosis and to expedite treatment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nasir Shahrestani
11/05/2007

SUPERVISORY